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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,978	11/15/2006	Martin Pruschy	4-32911A	3436
1095	7590	12/18/2009	EXAMINER	
NOVARTIS			GEMBEH, SHIRLEY V	
CORPORATE INTELLECTUAL PROPERTY			ART UNIT	PAPER NUMBER
ONE HEALTH PLAZA 104/3			1618	
EAST HANOVER, NJ 07936-1080				
MAIL DATE		DELIVERY MODE		
12/18/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,978	Applicant(s) PRUSCHY, MARTIN
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 September 2009.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5 and 11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1668)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/11/09 has been entered.
2. Applicant's arguments filed 9/16/09 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-5 and 11 are pending in this office action.
5. The rejection of claims 1-5 under 35 U.S.C. 112, first paragraph, while being enabling for treating a solid tumor such as prostate, glioma and thyroid tumors as specified in the specification (page 2) with ionizing radiation, does not reasonably provide enablement for treating a wide variation of solid tumors in general is withdrawn

based on Applicant's arguments and because page 2 of the specification specifically lists the cancers that encompasses the term "solid tumors".

6. The rejection of claim 10 under 35 U.S.C. 112, first paragraph is withdrawn due to the cancellation of the claim.

7. The rejection of claims 1-5 under 35 U.S.C. 102(e) as being anticipated by Vite et al. (US 6,605,599) is withdrawn because Vite specifically exclude "with the proviso that the present invention does not include compounds wherein W and X are both oxygen. Based on that argument the rejection is withdrawn.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

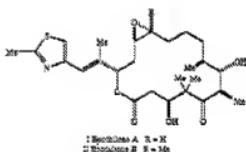
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danishefsky et al. (US Patent 6,242,469) in view of Bollag Exp. Opn. Invest. Drugs (1997) 6 (7):867-873 and Choy Critical reviews in Oncology/Hematology 37 (2001) 237-247.

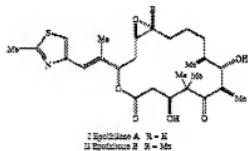
Danishefsky et al. teach pharmaceutical compositions of epothilones A and B



(i.e., $\begin{array}{c} \text{I: Epothilone A: R = H} \\ \text{II: Epothilone B: R = Me} \end{array}$) for the treatment of solid tumor in a subject, wherein the solid tumor is breast cancer (as required by instant claims 1-3, 5 and 11; see abstract and col. 28 line 49-56). Reasonably treatment of breast cancer in a subject meets the limitation of treating a warm-blooded animal (as required by instant claim 4).

However Danishefsky et al. fail to teach the combination of epothilone b in combination with ionizing radiation.

Bollag teaches numerous solid tumors may be treated with the compounds of



epothilones (i.e., $\begin{array}{c} \text{I: Epothilone A: R = H} \\ \text{II: Epothilone B: R = Me} \end{array}$) and further teaches that because of the similarity with a class of compounds (taxanes), epothilones possess similar or greater potencies than taxanes and should be further studied in combination with ionizing radiation.

Choy teaches a class of drug known as taxanes which are similar in chemical structure combined with ionizing radiation therapy in the treatment of solid cancers.

It would have been obvious to one of ordinary skill in the art to expand the method of Danishefsky et al. to include the methods of Bollag and Choy because both Bollag and Choy teach or suggest the inclusion of ionizing radiation in the methods for treating solid tumors.

The instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order form a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant method of treatment, given the teaching of the prior art methods of using Danishefsky et al. and Bollag and Choy individually for treating solid tumors, it would have been obvious to use both compounds for the treatment of solid tumors because the idea of doing so would have logically followed from their having been individually taught in the prior art to be useful as therapeutic agents.

9. No claim is allowed.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **SHIRLEY V. GEMBEH** whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **MICHAEL HARTLEY** can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
12/11/09

/Robert C. Hayes/
Primary Examiner, Art Unit 1649